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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/796,604

03/08/2004

Richard S. Bein

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38706

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03/27/2008

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EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

03/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/796,604	Applicant(s) BEIN ET AL.	
	Examiner JAGADISHWAR R. SAMALA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/7/2004 & 9/24/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

10796DETAILED ACTION

RCE Acknowledged

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/14/2008 has been entered.

Inventorship

2. In view of the papers filed 02/14/2008, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding inventors: Brain M. Strauss and Brain Canfield.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Response to Declaration under C.F.R. § 1.132

3. Applicant's Declaration of Brain M. Strauss, submitted under C.F.R. 1.132 filed on 02/14/2008 has been received and entered into the application. However, an affidavit

asserting unexpected results cannot overcome 102 rejection where the product and its use were known before the applicant's filing date.

Status of Application

4. Acknowledgement is made of amendment filed on 02/14/2008. Upon entering the amendment, claims 9 and 17-23 are cancelled and claim 1 is amended. The pending claims are 1-8 and 10-16 and presented for examination.

Previous rejections that are not reiterated herein are withdrawn. However, new ground(s) of rejection is made due to the scope changes made into the newly amended claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "from greater than about" in claims renders the claims indefinite, because it is not clear greater than about contains greater than 40 and about contains 40. The metes and bounds of the claims, accordingly, one of ordinary skill in the art would not be able to reasonably appraise the scope of the invention.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 4-8 and 10-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Whalen et al. (US 2002/0090339 A1).

With respect to claims 1-8 and 10-16, Whalen discloses a composition for embolizing blood vessels suited for treating vascular lesions via catheter deliver. And composition comprising: a biocompatible polymer at a concentration of from about 2 to about 50 weight percent; and a biocompatible contrast agent at a concentration of from about 10 to about 40 weight percent; and a biocompatible solvent from about 10 to about 88 weight percent wherein the weight percent of the biocompatible polymer, contrast agent and biocompatible solvent is based on the total weight of the complete composition (see abstract and para 0032-0035). And preferred biocompatible polymers include cellulose acetates, ethylene vinyl alcohol, copolymers, hydrogels, polyacrylonitrile, polyvinylacetate, cellulose acetate butyrate, nirtocellulose, copolymers of urethane/carbonate, copolymers of styrene/maleic acid, and mixtures thereof (see 0060). And water insoluble contrast agents include tantalum, tantalum oxide, and barium sulfate of particle size of about 10 microns or less and more preferably at from about 1 to about 5 microns (see para 0067 and 0078). And biocompatible solvent includes ethyl lactate, dimehtylsulfoxide, ethanol, acetone and the like (see 0069).

Therefore, all the critical elements as required by instant claims are taught by the cited reference and claims are anticipated.

3. Claims 1-2, 4-8 and 10-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Patterson et al. (US 2004/0224864 A1).

With respect to claims 1-8 and 10-16, patterson discloses a sterile embolic composition suitable for embolizing a vascular site in a mammal. And composition comprising a biocompatible polymer from about 1 to about 12 weight percent; a biocompatible water insoluble contrast agent from about 20 to about 55 weight percent and a biocompatible solvent that is miscible in blood and other body fluids and serves to solubilize the biocompatible polymer (see abstract and para 0193). And biocompatible polymer can be either biodegradable or, preferably, non-biodegradable include cellulose acetates, ethylene vinyl alcohol, copolymers, hydrogels, polyacrylonitrile, polyvinyl - acetate, cellulose acetate butyrate, nirtocellulose, copolymers of urethane/carbonate, copolymers of styrene/maleic acid, and mixtures thereof (see para 0133). And water insoluble contrast agents include tantalum, tantalum oxide, and barium sulfate of particle size of about 10 microns or less and more preferably at from about 1 to about 5 microns (see para 0129 and 0160). And biocompatible solvent includes ethyl lactate, dimethylsulfoxide, ethanol, acetone and the like (see 0139). Therefore, all the critical elements as required by instant claims are taught by the cited reference and claims are anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whalen et al. (US 2002/0090339 A1) or Patterson et al. (US 2004/0224864 A1) in view of Evans et al. (US 5,695,480)

Whalen et al. or Patterson et al meets the claim limitations as described above but fails to disclose explicitly the ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent is about 0.070 or greater.

Evans discloses compositions comprising biocompatible polymer from about 2.5 to about 8.0 weight, biocompatible contrast agent from about 10 to 40 weight and biocompatible solvent such as DMSO from about 52 to about 87.5 weight (see col. 3,

lines 32-43). The teachings of Evan et al. provides a motivation and expectation of success by using the ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent is about 0.0625 in embolic composition comprising similar component used in overlapping range of concentrations as those claimed in the instant application.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to combine the teachings of Whalen et al. or Patterson et al. and Evans et al. to make an embolic composition comprising the desired ration of biocompatible polymer to the water-insoluble biocompatible contrast agent. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention was made to generate a composition comprising a non-reactive biocompatible substance, a theologically modified a c biocompatible polymer to contrast agent ratio because the cited references and applicant disclose compositions comprising such components.

One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended therapeutic modalities to improve patient's compliance by enhancing patient satisfaction and increasing the selection option. The techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan as evidenced by these references cited.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same

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ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01 (a).

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 4-8, 10-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,667,767 and claims 1-8 and 16-23 of U.S. Patent No. 5,695,480. Although the conflicting claims are not identical, they are not patentably distinct from each other because US '767 and '480 claim a composition comprising a polymer, including polyvinylacetate, cellulose acetate butyrate, nitrocellulose, and copolymer of urethane/carbonate and styrene/maleate, a solvent which solubilizes the polymer, including dimethylsulfoxide,

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an insoluble contrast agent, including tungsten, gold, and platinum, and 0.1-25 % water insoluble radioisotopes.

The instant application claims a composition comprising 2 to 40 % of a biocompatible polymer, including polyvinylacetate, cellulose acetate butyrate, nitrocellulose, copolymers of urethane/carbonate or styrene/maleic acid, biocompatible solvent dimethylsulfoxide, and a biocompatible water-insoluble contrast agent including barium sulfate, tantalum, tantalum oxide, gold, tungsten, or platinum. Embolizing blood vessels is disclosed (page 7 lines 16-17). Thus, the claim is readily envisaged by the teaching of the prior art and the claim is properly included in the rejection.

Conclusion

1. No claims are allowed at this time.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Jagadishwar R Samala/
Examiner, Art Unit 1618